

REMARKS/ARGUMENTS

In a prior amendment, claims 1-20 were canceled. In the present amendment, claims 30, 32-33, and 39-40 have been canceled. New claims 41-43 have been added. After entry of the present amendment, claims 21-29, 31, 34-38 and 41-43 will remain in this application.

Support for specific elements in the amended claims may be found, for example:

for “water deprivation”, in Figures 6A-6D, on page 16, line 25, on page 68 in Table 4 for the row for SEQ ID NO: 193: “Abiotic stress; Drought: Increased tolerance to drought in a soil-based assay”, on page 371, lines 33-35, and on page 410, lines 12-18 and 36;

for “the conserved domain is required for a function by the polypeptide of regulating transcription and the polypeptide confers to the transgenic plant greater tolerance to water deprivation than a control plant” with the conserved domain having at least 70%, 80% or 85% identity to a conserved domain of a polypeptide of the invention (i.e., in the sequence listing): on page 14, lines 6-10, page 23, line 13, and claim 1 as filed; and for a “vascular specific promoter” used in claim 28; on page 54, lines 12 and 22.

Applicants believe no new matter is added by this amendment. This amendment is being made in response to the Final rejection and to respond to issues raised in an interview with the Examiner, and was not made previously for these reasons.

Examiner interview conducted on June 2, 2006, between Stuart F. Baum, Ph.D., Examiner, and Jeffrey M. Libby, Ph.D., agent for Mendel Biotechnology, Inc.

Background: The present application stands rejected based for lack of sufficient written description and enablement, said rejections raised by the Examiner in the final Office action.

Applicants’ summary: In this interview, Dr. Libby noted that the polypeptide sequence being claimed, G1274, SEQ ID NO: 194, was disclosed in the specification to confer a number of traits, including larger leaves and greater biomass, and greater tolerance to cold, water deprivation, and nitrogen limitation. The application presently claims a transgenic plant and a method for producing same, wherein the transgenic plant comprises a polypeptide comprising a conserved domain that has at least 70%, 75% or 80% sequence identity to a conserved domain of amino acid coordinates 111-164 of G1274 polypeptide, SEQ ID NO: 194. Dr. Libby noted that the present specification discloses how to identify sequences related by percentage identity, and even discloses a number of closely related sequences that fall within the scope of the claims and have been shown to function similarly by conferring similar traits as found in plants overexpressing G1274. These sequences were described as orthologs of G1274: “Table 7 lists sequences discovered to be orthologous to a number of representative transcription factors of the present invention”, and were publicly known sequences or were provided in the Sequence Listing. These include, for example SEQ ID NO: 969, 970, 971, 974, 975, and public sequences BM334368, and BQ742659, among others. Dr. Libby noted that all of these sequences conferred traits similar to those conferred by G1274, noted in the previously filed declaration by Dr. Peter

Repetti. Based on previous discussion Dr. Libby had with Dr. Baum for an unrelated application, Dr. Libby asked whether Dr. Baum was still of the opinion that each sequence tested that was encompassed by the claims (that is, that had a minimum percentage identity) had to confer all of the traits being claimed. Examiner Baum replied that he maintained that opinion.

Dr. Libby asked if one or a few sequences failed to produce said trait(s) but a majority were shown to produce the trait, whether that trait could be claimed. Dr. Libby maintained that, given a representative number of functional species, one or a few non-functioning examples should be permissible. Examiner Baum is considering the matter.

The other concern for Examiner Baum was whether it was generally appropriate to claim percentage identity to a domain. Dr. Libby responded that he knew of at least several issued US patents that claimed percentage identity to domains of protein sequences, and could supply a list of some of those patents if need be. Dr. Baum indicated that he would discuss that matter with others at the USPTO to ensure that this was acceptable practice.

Dr. Libby suggested amending the claims to include transgenic plants that conferred improved traits, and methods of making same, wherein all or almost all of the sequences encompassed by the invention have been shown to confer said traits. It was agreed that claims to 70%, 75% or 80% identity to the aforementioned domain should not raise new issues as these were previously claimed.

Office action, item 6, rejection under 35 U.S.C. §112, first paragraph, written description

The rejection for lack of written description has been avoided in part by the amendment to the claims, and is respectfully traversed for the following reasons.

The presently amended claims are directed to transgenic plants, methods for producing transgenic plants that have greater tolerance to water deprivation than control plants, and methods for increasing the tolerance of a plant to water deprivation, wherein the transgenic plants of the claims comprise a polypeptide having a conserved domain with at least 70%, 80% or 85% sequence identity to the conserved domain of amino acid coordinates 111-164 of the G1274 polypeptide.

The Examiner has stated that “[t]o fulfill the written description requirement for Applicants’ broad claims, Applicant is required to disclose other polynucleotide sequences encoding proteins comprising the specified conserved domain, wherein the conserved domain has at least 70% amino acid identity to amino acid coordinates 111-164 of SEQ ID NO: 194 at the time of filing” (page 5, paragraph 3 of the Office action) and that Applicants have only disclosed one domain that is characteristic to the claimed genus, i.e., amino acids 111-164 of SEQ ID NO: 194” (page 6, paragraph 1 of the Office action).

With regard to sequence relatedness, Applicants taught how to identify closely-related sequences in their specification (see, for example, page 36, lines 17-33, page 37, lines 12-20, on page 39, lines 25-36 and on page 119 line 27 through page 120 line 16. Applicants disclosed G1274 (SEQ ID NO: 194), and showed

that was this sequence was able to confer greater tolerance to water deprivation and other abiotic stresses to plants. Applicants described the full scope of the presently amended claims at the time of filing by describing polynucleotide sequences encoding proteins comprising the conserved domains having at least 70%, 80% or 85% amino acid identity to amino acid coordinates 111-164 of SEQ ID NO: 194. Conserved WRKY domains, such as that found in SEQ ID NO: 194 (page 82, Table 5, last row), are known in the art. See, for example, Ishiguro and Nakamura (1994) *Mol. Gen. Genet.* 244: 563-571 (reference identified in the specification on page 18, line 32), or NCBI locus no. NM_125877, revision of Aug 20 2002 4:49 PM for “gene= At5g64810” which “contains Pfam profile: PF03106 WRKY DNA -binding domain” (the gene identifier was disclosed on page 409, lines 31-32). It would also be a matter of routine to identify WRKY conserved domains of sequences closely related to SEQ ID NO: 194, for example, by BLAST analysis of SEQ ID NO: 194 against a database of sequences such as the NCBI conserved domain database, said method and database known in the art at the time of filing (e.g., Marchler-Bauer et al. (2002) *Nucleic Acids Res.* 30: 281-283, reference previously submitted). Software for performing BLAST analyses was also identified on page 119, lines 29-30 or page 120, lines 13-14 of the specification, and for identifying annotated motifs with BLOCKS, PFAM, and other databases, on page 40, lines 32-34 of the specification. Applicants also disclosed in the Sequence Listing and in Tables 7 and 9 of the application a number of sequences that are phylogenetically-related to G1274 and that fall within the scope of the present claims, that is, that have 70% or more identity to the WRKY conserved domain of SEQ ID NO: 194.

With regard to a description of function of these related sequences, Applicants disclosed on page 13, lines 6-10, “nucleotide sequences encoding a polypeptide having a conserved domain *required for the function of regulating transcription and altering a trait* in a transgenic plant, *the conserved domain being at least 70% identical with a conserved domain of a polypeptide of the invention* (i.e., a polypeptide listed in the sequence listing, or encoded by any of the above nucleotide sequences)” (*emphasis added*). On page 16, lines 23-26 the specification describes “Figures 6A - 6D compare soil-based drought assays for G1274 overexpressors and wild-type control plants, which confirms the results predicted after the performance of the plate-based osmotic stress assays. 35S::G1274 lines fared much better after a period of *water deprivation* (Figure 6A) *than control plants* (Figure 6B) (*emphasis added*).” Applicants also described how “[t]he enhanced performance of 35S::G1274 plants in a soil-based drought assay indicated that the gene *or its equivalents* may be used to enhance drought tolerance in plants (*emphasis added*).

Applicants have overexpressed in plants a number of sequences that are encompassed by the claims, including several of the sequences in Table 7 of the specification, and have shown that these sequences, similar to G1274, confer greater water deprivation tolerance than the level of water deprivation tolerance found in control plants (see attached declaration by Dr. Repetti). The examples in Table 7 that have been shown to function in this regard include SEQ ID NOs: 969 from soy, 971 from rice, and 974, and 975 from

corn. In the attached declaration, Applicants also demonstrated that several G1274-related sequences with somewhat *less* than 70% identity to the conserved WRKY domain of SEQ ID NO: 194 were able to confer water deprivation tolerance in plants when overexpressed, underscoring the veracity of Applicants' "broad claims".

With the presently claimed invention being thus described, and in light of these amendments, arguments and experimental observations with closely-related functional examples from diverse species confirming Applicants' disclosure and claims, Applicants request that the rejection under 35 U.S.C. §112, first paragraph, written description, be withdrawn.

Office action, item 7, rejection under 35 U.S.C. §112, first paragraph, enablement

The rejection for lack of enablement is avoided in part by the present amendment, and is respectfully traversed for the following reasons.

In the most recent Office action, the Examiner has stated that "Applicants have disclosed one nucleic acid sequence encoding SEQ ID NO: 194 that when overexpressed in plants alters the traits listed in claim 24. Applicants have not disclosed other sequences that encode proteins comprising a conserved domain that has at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO: 194 and produces a plant with all the traits listed in claim 24. Applicants have not disclosed other conserved domains that are required for the proper activity of the protein. Applicants have not disclosed how one skilled in the art distinguishes between those sequences that produce the desired traits versus those that don't even though they both encode proteins comprising a conserved domain that has at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO: 194."

However, as Applicants have noted above, Table 7 of the specification provides sequences from dicots and monocots and the specification indicates that the invention encompasses sequences with at least 70% sequence identity to amino acid coordinates 111-164 of SEQ ID NO: 194 that regulate transcription and confer an altered trait. In the case of G1274 and related sequences that altered trait is the function of more water deprivation tolerance in transgenic plants overexpressing G1274, relative to control plants. Table 7 provides SEQ ID NOs: 969 from soy, 971 from rice, and 974 and 975 from maize. Tables 7 and 9 of the specification identifies these and other sequences as orthologous to G1274, the specification describes the invention as "orthologous and paralogous nucleotide sequences that are at least 70% identical to any of the nucleotide sequences [found in the sequence listing]" (e.g., on page 14, lines 1-2), and as disclosed and known in the art, orthologs are "functionally homologous sequences" (e.g., page 36, line 10), "that have similar sequence and similar functions" (e.g., page 36, lines 13-14), and "often have an identical function within their host plants and are often interchangeable between species without losing function" (page 36, lines 35-37).

Applicants have also taught how the skilled artisan may find related sequences. Conserved WRKY domains, such as that found in SEQ ID NO: 194 (page 82, Table 5, last row), are known in the art (see, for example, Ishiguro and Nakamura (1994) *Mol. Gen. Genet.* 244: 563-571, identified in the specification on page 18, line 32, or NCBI locus no. NM_125877, revision of Aug 20 2002 4:49 PM for “gene= At5g64810” which “contains Pfam profile: PF03106 WRKY DNA -binding domain”, the gene identifier disclosed on page 409, lines 31-32), and it would be a matter of routine to identify WRKY domains of sequences closely related to SEQ ID NO: 194 (for example, by BLAST analysis of SEQ ID NO: 194 against the a database of sequences such as the NCBI conserved domain database (Marchler-Bauer et al. *supra*), the software for performing BLAST analyses identified on page 119, lines 29-30 or page 120, lines 13-14). Applicants routinely perform such analyses, and the conserved domains of G1274 and related sequences were readily identified and provided in Appendix B attached to the February 13, 2006 declaration of Dr. Repetti. As sequences found in Tables 7, 9 and the sequence listing were also disclosed, the WRKY domains of these sequences were thus disclosed, and it would be a matter of routine for the skilled artisan to identify the WRKY domains within these sequences, including those of SEQ ID NOs: 969, 971, 974 and 975 which confer water deprivation tolerance. The conserved domains of these sequences were readily identified and provided in the Appendix B attached to the February 13, 2006 declaration of Dr. Repetti.

Significantly, Applicants have indeed disclosed how one skilled in the art may distinguish between those sequences that produce the desired traits versus those that don't. Every sequence closely related to G1274 that was tested in soil drought assays has produced a strongly positive result; G1274 SEQ ID NOs: 193 and 194) G3724 (SEQ ID NO: 969), G3804 (SEQ ID NO: 974), G3721, G3726 (SEQ ID NO: 971), and G1275 all conferred significantly improved drought tolerance relative to controls. Additionally, G3803, G3722 (SEQ ID NO: 975) G3729, G2517 and G194 conferred water deprivation tolerance in plate-based assays (soil-based drought tolerance studies with these sequences have not yet been performed). No sequence for which Applicants have performed the full range of water deprivation analyses has failed to produce transgenic plants that were more water deprivation tolerant than control plants.

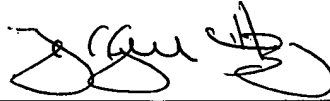
Since Applicants readily identified sequences that have conserved domains at least 70% or more identical to the similar domain of G1274, and that confer increased water deprivation tolerance in plants, it would thus be a matter of routine for the skilled artisan to distinguish between those sequences that produce increased water deprivation tolerance versus those that don't. Therefore, since there is a high likelihood of finding functional examples of G1274-related sequences, including examples from diverse species, Applicants request that the rejection under 35 U.S.C. §112, first paragraph, enablement, be withdrawn.

Application No. 10/666,642
Amendment dated June 26, 2006
Reply to Final rejection of May 18, 2006

CONCLUSION

Applicants believe that, other than the fees associated with the attached RCE, no additional fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Mendel Biotechnology, Inc. Deposit Account No. **50-1025**.

Respectfully submitted,
MENDEL BIOTECHNOLOGY, INC.



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Date: June 26, 2006

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Attachments:
Declaration under 37 CFR 1.132 OF Peter Repetti

JML/jml
File: MBI-0054US.RFR.doc